

REMARKS

Claims 1-9, 14 and 15 were previously pending and claim 16 is added in this reply. So claims 1-9 and 14-16 are now pending.

Rejections under the first paragraph of 35 USC § 112

Claims 1-9, 14, and 15 stand rejected under 35 U.S.C § 112, first paragraph, as allegedly failing to comply with the written description requirement based on alleged absence of basis in the specification for claims 1 and 3, claiming water soluble flavoring in the range from 0.1% to 1.5% and the range from 0.2 to 1.5%, respectively. The applicant will first review the law pertaining to written description as applied to amendments.

1. It is not necessary that the application describe the claim limitations exactly...but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that appellants invented processes including these limitations. In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976)

2. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter". *In re Kaslow*, 707 F.2d 1366, 1375, 217 U.S.P.Q. (BNA) 1089, 1096 (Fed. Cir. 1983).
3. Precisely how close the original description must come to comply with the description requirement of 35 U.S.C. § 112 must be determined on a case-by-case basis. *In re Wilder*, 736 F.2d 1516, 1520, 222 U.S.P.Q. (BNA) 369, 372 (Fed. Cir. 1984).
4. Federal Circuit Ruling on Ranges. Eiselstein's assertions regarding this point. Since the grandparent application only disclosed a nickel range of 45-55%, it can hardly be said to have disclosed 50-60%. Whatever the term "about" means in this context, it is clear that it does not extend 55% to encompass 60%. Moreover, the 10% range of 45-55%, even if it is an approximate "about" 45-55%, is not the same as a very different 10% range viz., 50-60%. The limits of these ranges vary from each other by about 10%, which is comparable to the extent of the variation within each range. *Eiselstein v. Frank*, 52 F.3d 1035 (Fed. Cir. 04/11/1995)
5. "that a claim may be broader than the specific embodiment disclosed in a specification is in itself of no moment." *In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. (BNA) 323, 326 (CCPA 1981).
6. In establishing a disclosure, applicant may rely not only on the description and drawing as filed but also on the original claims if their content justifies it. MPEP 608.01(l)

The disclosure of flavor ranges in the specification is as follows:

1. On page 3, lines 14-16, a range from about 1% to about 1.4% of water soluble flavoring is disclosed. The range comes about because there is a range of water content varying from about 8% to about 35% water with a single value of about 1% water soluble flavoring for the whole range of water concentrations. The final product as claimed must contain 8% water. Therefore, 1% flavoring at 35% water must be corrected to a dried 8% water capsule having 1.4% flavoring.

2. On page 5, lines 23-25, the preferred embodiment at the time of filing is disclosed as being made from a gelswatch of 35% water and “0.5% or more of strawberry flavor Firmenich #52311A” (misquoted in the OA). This corresponds to 0.7% or more of flavoring in a dried capsule having 8% water. The prior paragraph (lines 16-21 on page 5) makes it clear that Firmenich #52311A flavoring is just a preferred example and that other suitable gelatin capsule flavorings known in the art can be used in its place. (A list of suitable flavors known in the art is enumerated on page 3, lines 20-23).
3. In the paragraph bridging page 6 and page 7, “flavoring agent of about 0.25% to about 0.5% when Omega 3 is present at 80%” is disclosed.
4. On page 6, line 21, a level “in excess of about 1% of Firmenich #52311A” is recommended.
5. This application is a continuation of 10/292,999, which is a continuation of 10/041,877, which was a continuation of 09/416,017 now U.S. Patent 6,346,231. The entire contents of the grandparent, 09/416,017 are incorporated by reference in the child, 10/041,877, which is incorporated by reference in the grandchild, 10/292,999, which is incorporated by reference in the instant application. The original claims in the grandparent are therefore part of the disclosure and are incorporated by reference in this application. Original claim 2 of the grandparent reads as follows:
“A flavored gelatin capsule, said capsule encapsulating a dose, said gelatin capsule comprising:
 - (a) about 10 to about 70 parts by weight of gelatin;
 - (b) about 10 to about 35 parts by weight of a polyol;
 - (c) about 8 parts by weight of water
 - (d) up to about 0.5 parts by weight of a water soluble flavoring, whereby said flavoring of said capsule improves the palatability of said capsule and the dose, and ingestion of the dose is encouraged.”.

Element (d) of original claim 2 of the grandparent has been amended by reference into the specification of the instant application.

Analysis

The applicant argues that in this case, a person of ordinary skill in the art would be a person capable of understanding the recipes in the patent application, formulating a gelswitch to make flavored gel caps, and processing the gelswitch through an encapsulating machine, and drying the capsules.

It is not necessary that the application describe the claim limitations exactly...but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that appellants invented processes including these limitations. In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976)

Applicant argues that this person of ordinary skill in the art would recognize that the application discloses a number of sub-ranges that can be joined together to yield the claimed ranges of water soluble flavoring. The sub-ranges include (all corrected to 8% water content).:

- a) About 1% to about 1.4% of soluble flavoring
- b) 0.7% or more of soluble flavoring
- c) About 0.25% to about 0.5% of soluble flavoring
- d) In excess of about 1 % flavoring
- e) Up to 0.5% of soluble flavoring

The applicant submits that the person of ordinary skill in the art would recognize the ranges of about 0.1% to about 1.5% (claim 1), 0.2% to about 1.5% (claim 3) and about 0.25% to about 1.4% (new claim 16). The applicant respectfully requests reconsideration and removal of the rejections under the first paragraph of 35 USC § 112.

Rejections under 35 USC § 103

Claims 1-9, 14, and 15 stand rejected under 35 U.S.C 103 (a) as being allegedly unpatentable over Lachman et al. in combination with US 5,955,102 ('102) and US 5,718,323 ('323). Lachman teaches 0.1% of ethyl vanillin and essential oils not to exceed 2%. '102 teaches that fish oil is preferably provided in a gelatin capsule. The OA

concludes that the combination of Lachman and ‘102 does not teach water soluble flavors.

‘323 teaches a soft gelatin capsule comprising flavoring agent selected from essential oils and fruit flavour or combinations thereof (col. 5, lines 43-49).. All of the examples of essential oils and flavours were present in quantities between 4.8% and 6%. The OA concludes that “fruit flavors are expected to be water-soluble since compounds and their properties are inseparable” and relies on this conclusion for the showing that all of the elements of the claim were known in the prior art.. Applicant respectfully traverses this conclusion. Applicant submits the following excerpt from the Nature’s Flavors on-line catalogue (www.naturesflavors.com) as evidence that fruit flavors may be oil soluble.

“Nature’s flavors pure fruit oils are made with the finest and most pure oils. These oils are the strongest flavor oils we offer, many of them are over 60,000 times stronger than the fruits that they came from. To illustrate imagine the flavor of one strawberry and then imagine this pure flavor oil which may be 60,000 times more flavorful than the single strawberry. How is that possible? If you were to break down that strawberry to the basic building blocks and discard the water, sugar, natural pectin, acids, and fiber or pulp, only the flavor would remain. Reconstituted, only the natural pure oils would remain.

Now for some of the oils it is not possible for us to extract every component of the strawberry from the strawberry so we can often times gather the ingredients from other sources where it is much more plentiful. The notation WONF means with other natural flavors. These flavors are naturally extracted and added back into the strawberry flavor.

These flavors are so strong that they should not be used by beginners. However, for those of us with more experience working with flavors, these pure oils save time and money while giving incredible flavor to our recipes.

These pure flavor oils are oil soluble and can only be used in oil based formulations and in making extracts. To make these flavors water based, homogenize in gum Arabic solution at a ratio of one part oil to six parts gum Arabic solution. Gum Arabic solution can be found at **Nature’s Flavors** or at other locations.”

“All words in a claim must be considered in judging the patentability of that claim against the prior art”, In re Wilson, 424 F.2d 1382, 1385 (CCPA 1970) and MPEP 2143.03. Claims 1d, 3, and 16 require the presence of a water-soluble flavoring in the range of about 0.1 to about 1.5, about 0.2 to about 1.5, and about 0.25 to about 1.4%

respectively. None of the prior art references, either alone or in combination, teach a water-soluble flavoring **in these ranges**.

Lachman teaches only two flavorings, one of which is insoluble (ethyl-vanillin) and one of which is not sufficiently enabled to discern whether it was soluble or insoluble (essential oils). ‘323 teaches essential oils and doesn’t state whether the fruit flavours were soluble or insoluble (as shown in the excerpt above they could have been either). ‘323 certainly did not recognize the importance of using water soluble flavorings or it would have stated which it was. Neither the essential oils of Lachman nor the essential oils and fruit flavorings of ‘323 suggest the surprisingly narrow ranges recited by the claims and shown in the Opheim declaration as discussed below. In fact ‘323 examples used 4.8% to 6% of flavoring, in sharp contrast to the ranges recited by the instant claims.

It is argued that since there was no suggestion in the prior art to use water-soluble flavoring in the presently-claimed ranges, and the prior art only identified flavorings that were water-insoluble or may or may not have been water soluble, it would not have been obvious to one of ordinary skill in the art to use water-soluble flavorings in the range of amounts recited by the claims. Applicant respectfully requests reconsideration of the 35 U.S.C. § 103 rejections and allowance of claims 1-9, and 14-16.

Objective Evidence

Applicant previously introduced a Declaration under 37 CFR 1.132 from Dr.Oliver B. Cooperman, M.D. of Rimrock Foundation in Billings, Montana who is frequently in a position to prescribe Nordic Naturals ®ProEPA and ProOmega to his patients in his medical practice. In the declaration, he attests that these products satisfy a long felt need recognized by physicians for palatable fish oil formulations which achieve patient compliance to take the formulations as prescribed. Both of these formulations contained 1% lemon flavoring in the shells. Dr Cooperman attributes the improvement to be largely

attributable to the flavoring in the shells. The OA criticizes this declaration as being insufficient because there was no “comparative data between the claimed amount of the flavor with amounts outside the upper and lower ends of the claimed range”. However, Dr. Cooperman states “I have observed that the above identified formulation is much more palatable to patients than other formulations, and largely resolves the long felt need for a palatable Omega-3 Fish oil supplement. I attribute the improvement to be to a large extent due to flavoring added to the gelatin shells. I believe that patient compliance is substantially improved with this formulation, compared to others which are available.”

This statement seems to supply the requested comparison. Applicant respectfully requests reconsideration of the declaration as an objective evidence of non-obviousness by satisfaction of a long felt need under the Graham Factors

Summary of Previously Submitted Objective Evidence

Applicant respectfully requests reconsideration of previously submitted Objective Evidence in light of the additional arguments herein set forth.

Applicant submitted a **Declaration showing unexpected results on 4/10/2006**, which was said in the OA to be unpersuasive because “the scope of the claims was broad covering all flavors in any amounts greater than 0.2%, while the declaration was limited only to one flavor Firmenich #52311A at a specific concentration of 0.5 to 1.0%”. Indeed at the bottom lines of page 7 of the declaration, the declarant states “that suitable flavoring occurred within a surprisingly narrow range of concentrations between about 0.25 and 1.5% flavoring”. **This now corresponds almost exactly to the scope of the amended claims. While the declarant only gave detailed sample lab data for one flavoring, he declared that similar results had been obtained from testing at least ten**

different natural flavorings, including strawberry, peppermint, lemon, peach, orange and plum (see top of page 8). Also declarant states in his summary that “the flavor content for a palatable capsule was between 0.25 and 1.25% for a wide variety of natural flavors”. The Applicant submits that if there was a perceived discrepancy between the claimed invention and the declaration, it certainly does not exist for the amended claims.

Applicant also submitted a **Declaration Showing Commercial Success** on 9/25/2006. In that declaration he indicated that Flavored Gel Caps made by Nordic Naturals, Inc. all in accordance with the **claimed** invention, and having approximately 1% flavoring in gelatin shells, **had captured approximately 43% of the United States market for fish oil capsules sold in Health Food Stores in July 2006, certainly evidence of commercial success by any standard.**

It is also respectfully submitted that the objective or secondary considerations are both relevant and probative under Graham v. John Deere, proving unexpected results, commercial success and long felt need. Thus, even assuming *arguendo* that the Patent Office can show *prima facie* obviousness of the instant claims, Applicant has provided sufficient secondary evidence to rebut any such conclusion and demonstrate the non-obviousness of the presently claimed invention.

For all of these reasons Applicant respectfully requests allowance of all outstanding claims and timely issuance of a Notice of Allowance.

Respectfully Submitted,

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